December 13, 2010

Donald M. Berwick, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Margaret A. Hamburg, Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Room 2217
Silver Spring, MD 20993

Re: Parallel Review of Medical Products (FDA-2010-N-0308)

Dear Administrator Berwick and Commissioner Hamburg:

Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration. Section 612 of the Regulatory Flexibility Act (RFA) also requires Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.[1]

On September 17, 2010, The Centers for Medicare and Medicaid Services (CMS) and the U.S. Food and Drug Administration (FDA) published in the *Federal Register* a notice (notice) requesting public comment on parallel review of medical products.[2] The agencies indicate in the introductory section of the notice that they are considering establishing a process for overlapping evaluations of premarket, FDA-regulated medical products when the product sponsor and both agencies agree to such parallel review. The notice asserts that, "this process will serve the public interest by reducing the time between FDA marketing approval or clearance decisions and CMS national coverage determinations (NCDs)."[3]

[1] Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat.857 (1996). 5 U.S.C. §612(a).
[2] 75 Fed. Reg. 57045 (September 17, 2010).
[3] Id.

My office was approached by interested stakeholders, including the National Venture Capital Association (NVCA) Medical Innovation and Competitiveness (MEDIC) Coalition. The aforementioned stakeholders are comprised of venture capital, medical device, and biotechnology companies. Many are small businesses as defined by the SBA's size standards. In light of the critical role that venture capital dollars play in medical innovation in this country, the stakeholders asked Advocacy to relate the industries' concerns with parallel review to CMS and FDA as any proposed rule that results from the notice will likely have a significant economic impact on their businesses. While implementation issues surrounding parallel review have yet to be proposed as a regulation, Advocacy hopes that CMS and FDA will take the following industry concerns into consideration and, pursuant to the requirements of the RFA, analyze any economic impacts associated with any parallel review rule established by the agencies.

Affected stakeholders told Advocacy that they welcome the policy goal underlying this notice, "to accelerate consumer access to new and particularly innovative, safe and effective products."[4] However, they want to ensure that any parallel review process is voluntary, transparent, predictable and beneficial. Stakeholders believe that the majority of new medical technologies would not need to take advantage of the parallel review pathway. They suggest that prior to issuing a proposed rule CMS and FDA should outline for the medical technology industry how the parallel review process will work, how it will protect confidentiality, and discuss why the proposed review process will avoid duplication and improve efficiencies to an already existing regulatory process for new medical technology approval. The industry representatives that approached Advocacy are concerned that any proposal to effectuate a parallel review process may have the unintended consequence of creating delays in patient access to essential new technologies by imposing a new, national-level review.

The notice seeks public comment on 17 parallel review questions posed by the agencies. Affected stakeholders asked that Advocacy provide CMS and FDA with the following comments on the information sought in the notice. The comments follow the number of the question/s asked in the notice by CMS and FDA.

1. Should anyone other than the product sponsor be able to initiate a request for parallel review (for example, the FDA, CMS, an interested third party)?[5]

16. Once FDA and CMS have opened a parallel review should a sponsor be able to terminate, or withdraw the request for parallel review? If this happens, should that information be made public?[6]

Stakeholders told Advocacy that in their opinion any request for parallel review should be sponsor-initiated and voluntary. Allowing only the sponsor to request parallel review will ensure that the review is voluntary. They also suggest that it should be in the sole

[4] 75 Fed. Reg. 57046.
[5] 75 Fed. Reg. 57047.
[6] 75 Fed. Reg. 57048.

discretion of the sponsor to determine whether or not to publically disclose either a request for parallel review or any decision to withdraw from the parallel review process, without prejudice to any pending or future interaction between the sponsor and the agencies. The stakeholders believe that a mandatory parallel review process may work to the detriment on early-stage companies, many of which have limited financial resources and time to devote to the approval process.

2. For which classes of products would consumers, payers, or sponsors benefit most from parallel review? Why?[7]

Stakeholders believe that in most instances it would be inefficient and duplicative to require parallel review for innovative technologies. Instead they suggest that parallel review should be used as a specialized alternative to already existing regulations for approval and coverage of medical technologies.

The notice acknowledges that in most circumstances Medicare coverage exists without a NCD.[8] Stakeholders concur and submit that medical products rarely present coverage issues that need to be addressed at the national level through an NCD, a fact that is proven because NCD approval rate is generally low historically. In fact, NCD for new technologies is even more infrequent and the determination is made after the product has been on the market and been used by Medicare beneficiaries. The stakeholders are concerned that new medical products seeking FDA approval are often in the early stage of development and therefore the data usually required for CMS coverage determinations will be markedly limited. This predicament could adversely impact product utilization and adoption. Industry representatives agree that potential problems such as this highlight the importance of assuring that any parallel review process would be voluntary. They also ask that CMS clarify that product sponsors would not be required to obtain a NCD at the same time they are seeking FDA approval. They would also like some assurance that the agencies will approve a greater percentage of NCD requests so that the product sponsor will be able to determine whether it makes sense to voluntarily seek parallel review.

Under the circumstances the stakeholders suggest that parallel review may be appropriate for truly novel technologies that raise new regulatory process and clinical questions concerning safety, efficacy, or how best to measure improvements to patient outcomes. Industry representatives believe that these types of products may be most suited to the parallel review process because the technology will be unfamiliar to the agencies and there will be no existing baseline upon which to make product comparisons. The stakeholders agree that under these limited circumstances, a voluntary parallel review process may be warranted, appropriate and feasible.

[7] Id.
[8] 75 Fed. Reg. 57046.

11. Should FDA and CMS have access to the same data and information about the product during parallel review? (Note: Both agencies will protect the confidentiality of proprietary information used in the parallel review process, as they currently do under their respective approval/clearance and coverage processes.)[9]

12. It is CMS' policy to inform the public when it begins an NCD process for a particular product. However, under applicable statutes and FDA's regulations, the existence of a premarket application is considered confidential commercial information prior to approval or clearance unless the sponsor has publicly acknowledged the application. With the consent of the sponsor, should CMS make public that it has begun the NCD process, as part of parallel review, for a product still undergoing FDA premarket review? As a condition of the agencies' agreement to initiate parallel review, should a sponsor have to inform the public, or consent to the agencies informing the public, that the product will be evaluated under parallel review? If the sponsor declines to consent to disclosure, should it be permitted to request parallel review anyway, which would prevent CMS from disclosing the NCD process until after the product is approved by the FDA? How can the transparency of CMS' NCD process be reconciled with the need to retain confidentiality of certain commercial information?[10]

Stakeholders are particularly concerned with how CMS and FDA plan to maintain the confidentiality of proprietary information if the parallel review process is instituted as they assume that product information will be made available to both agencies during the review. They suggest that neither innovator companies nor venture capital companies would be eager to participate in parallel review if safeguards were not in place to protect intellectual property or trade secrets, including significant penalties for wrongful/improper disclosure. The industry representatives believe that at present the regulations governing protection of confidential information are not coterminous between CMS and FDA. Stakeholders believe that despite the August 2010 FDA-CMS memorandum of understanding in which the subject of confidentiality is discussed, the agencies should provide more rigorous legislative or regulatory assurances to the industry. They also ask that the agencies clarify the disparate regulatory treatment of products seeking FDA premarket application (treated as confidential) and those applying for NCD through CMS (treated as public).

15. What other concerns or considerations should the agencies take into account when developing a process for parallel review?[11]

The industry representatives believe that CMS and FDA should not chose to regulate parallel review if it results in creating hurdles to the marketplace. They are concerned that the parallel review process could inadvertently result in additional regulatory barriers that will make it more difficult for innovative medical products to get to market.

[9] 75 Fed. Reg. 57047.
[10] 75 Fed. Reg. 57048.
[11] Id.

Stakeholders include in their definition of "barriers" any new data requirements that would be used by CMS and FDA to determine a product's cost or comparative effectiveness (a collection of data that would not necessarily be required by either agency if serial approvals were sought independently). Industry representatives believe that neither CMS nor FDA have the authority to study the comparative effectiveness of marketed products as that authority resides with the Patient-Centered Outcomes Research Institute created by Congress.

Conclusion

Advocacy requests that CMS and FDA take the industries' comments into consideration as they create the regulatory framework for any parallel review process. Advocacy also encourages CMS and FDA to comply with the RFA requirement to analyze any impacts associated with any parallel review process on the industry and to entertain any reasonable alternatives that will serve to minimize those impacts. If you have any questions or concerns, please do not hesitate to contact me or Linwood Rayford at (202) 205-6533, or linwood.rayford@sba.gov.

Sincerely yours,

/s/

Winslow Sargeant, Ph.D.
Chief Counsel for Advocacy

/s/

Linwood L. Rayford, III
Assistant Chief Counsel Advocacy

Cc: Cass R. Sunstein, Administrator, Office of Information and Regulatory Affairs